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Title of Study: Using Pressure Detecting Insoles to Reduce Knee Loading

Sponsor: Arthritis Foundation

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this study regarding your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you suffer from knee osteoarthritis.

What is the purpose of this study?

The purpose of this study is to evaluate changes in your symptoms and the load you place on your knee during walking - before and after walking with specialized footwear containing an experimental shoe insert.

How many study subjects are expected to take part in the study?

It is expected that approximately 150 subjects with knee osteoarthritis will take part in this study conducted here at Rush University.

What will you be asked to do?

In order to participate in this study you must have knee osteoarthritis based on your pain severity and on an X-ray examination of your knees. The study clinician will review your medical history to determine whether you may possibly qualify for the study. If you meet the preliminary study criteria (requirements) and agree to participate, you will be asked to come to Rush University for a screening visit.

Screening Visit

During the screening visit, you will undergo the following screening procedures: a clinical evaluation including height and weight measurements, assessment of your knees, and range of motion of the hips and knees (hips and knees will be moved in various directions to see if their movement is limited). You will be asked to fill out questionnaires regarding the amount of pain you have at your joints, how you function in your home and community, and if you have had any previous foot or joint problems. The questionnaires should take approximately 30 minutes to complete. You will also have an X-ray of your knees. If you continue to meet the study criteria after the screening visit, you will return within 3 months for your baseline visit.

Randomization for Group Assignment: If you fulfill the screening criteria, you will be randomly assigned to one of two study groups.

Visit # 1-Baseline

Prior to arriving for visit #1, you will be randomly assigned to a treatment based on chance, like a flip of a coin. Neither you nor the study staff chooses your assigned group. You will have a 62.5% chance of being assigned to group 1 and a 37.5% chance of being assigned to group 2. All subjects will receive a new pair of study shoes containing one of two experimental pairs of shoe insoles and insole accessories, including a handheld device used to communicate with the shoe insoles, a charger for the handheld device, and rechargeable batteries for the insoles. Group 1 will receive and perform a specific training protocol with a shoe insole that measures foot pressure. Group 2 will receive and perform a different training protocol with a similar shoe insole that measures foot pressure.

At visit # 1, you will have a clinical evaluation including height and weight measurements, an assessment of your legs, and range of motion of the hips and knees. You will fill out questionnaires regarding pain, general function, and, at the completion of the visit, you will rate your comfort level using the shoes and insoles. You will be asked to sign an equipment loan agreement form which states that you will return the shoe insoles and insole accessories after you have completed the study, or, in the event you withdraw from the study, you will return all equipment at that time.

You will be fitted and provided with a new pair of study shoes. In addition to the shoes containing a standard shoe insole, you will also be provided a special study insole which has pressure sensors. You will be given specific instruction regarding your walking pattern based on your group assignment. You will be asked to perform specific training in your home or out in the community with your shoes, the shoe insoles, and the device which controls your shoe insoles.

You will be asked to train with the study shoes containing the study insoles for at least 6 hours per day, 6 days per week for 6 weeks. For approximately 15 minutes of this training time, you will interact with the insole connected with the device. For the remainder of the day, you are encouraged to wear the study shoes and insoles for as long or as little as you wish. You will be given a diary to keep a weekly record of how often you are training in the shoes containing the

special insole, and whether you experience any side effects. You will also record whether you take any pain medications for osteoarthritis or other new medications.

Additionally, you will have a detailed gait (walk) analysis performed. The gait analysis is a painless procedure. This will consist of you walking in front of a series of cameras. You will have small reflective markers placed on your feet, legs, hips, and trunk. You will complete several walking trials with your own shoes and the study shoes containing the study insoles. You may be asked and given instructions to slightly modify your walking during some of the walking trials to determine how different walking styles affect the load in your joints. You will also have digital photographs taken from the front, back, and sides of your hips and legs. These photographs will be evaluated to determine different angles of your leg alignment (positioning).

Upon completion of all walking trials, you will have completed the first study visit. This visit is anticipated to last 3 ½-4 hours. These are not all weather shoes or insoles, and they should not be worn outdoors during wet or icy conditions. The shoes are a neutral color (light gray or blue) walking shoe. You will be contacted by phone or email, depending on your preference, every 3-4 days to ensure any questions you may have are answered, and allow you to ask about any problems you may have with the study shoes and insoles. You can otherwise call or email the research coordinator at any time. The contact information can be found on the inside cover of your shoe/insole journal.

After 3 weeks of training with the shoes and insoles, you will return to the motion analysis laboratory for an additional walking test.

Visit # 2: Week 3

Three weeks after visit #1, you will return for your 2nd visit. During visit #2, you will undergo another clinical evaluation including height and weight measurements, assessment of your legs, and range of motion of the hips and knees. You will complete questionnaires regarding your pain and function. You will undergo a gait analysis similar to visit 1. You will return your first shoe/insole diary and it will be reviewed to determine how often you are wearing your study shoes, whether you had any side effects, and whether you have taken any pain medications for osteoarthritis or other new medications. You will receive your second and final shoe/insole diary.

The second walking test will be similar to the first test. Upon completion of all questionnaires and walking trials, you will have completed the 2nd study visit. This visit is anticipated to last 3-3 1/2 hours. All subjects will return home with the study shoes and insoles and asked to walk in the study shoes and insoles, as described above, for at least 6 hours per day, 6 days per week and continue to interact with the insole connected with the device for approximately 15 minutes of the training time. Once again, these are not all weather shoes or insoles, and should not be worn outdoors during wet or icy conditions.

Visit # 3: Week 6

Three weeks after visit #2, you will return for your 3rd and final visit. During visit #3, you will undergo a gait analysis similar to visits 1 and 2. You will return your 2nd shoe/insole diary.

Upon completion of all questionnaires and walking trials, you will have completed the 3rd and final study visit. This visit is anticipated to last 3 - 3 ½ hours.

The study insoles and insole accessories have to be returned to the researchers for analysis. You will be able to keep the shoes with the standard insole.

Follow-up questionnaire:
A study-completion questionnaire will be sent via mail to you following your final study visit.

How long will you be in the study?

The active study will last for approximately 6 weeks and will require a screening visit and three study visits to the study clinicians' office. The screening visit will last approximately 2 hours. The baseline visit will last 3 ½ -4 hours, and the final two visits will last 3 to 3 1/2 hours.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you will need a treatment not allowed on the study, your disease becomes worse, you are unable to wear the shoes as directed, or the study is canceled.

What are the possible risks of the study?

If walking causes you discomfort, then you may experience some discomfort with walking during the gait analyses. The distance that you will be asked to walk for each trial is approximately 10 meters (about 33 feet, or 10-15 steps). You may be asked to walk this distance 30-50 times during the tests with scheduled rest periods. In any walking exercise, there is the risk of falling.

People respond differently to footwear. Although there are no specific risks associated with the footwear involved in this study, it is possible that you may experience discomfort associated with the shoes and insoles that are provided to you. If the study clinician believes that the discomfort can be easily fixed, then appropriate changes will be made. Please inform the study staff if you are experiencing any discomfort.

Radiation Risks
The X-ray examinations that you will receive if you participate in this study all use radiation. All persons have a risk up to several percent, depending on age, of developing a cancer (or second cancer) over their lifetime, even if they receive no medical radiation at all. Medical radiation can increase that risk, however, depending on its dose and where in your body it is directed. In most cases, your cancer risk after receiving medical radiation is so slightly increased from your natural cancer risk with no medical radiation that the difference is hard to measure.

Are there any anticipated pregnancy risks? Women

If you are pregnant or breastfeeding, you cannot take part in this study. If you become pregnant, you must notify the study doctor immediately.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.** It may be possible that you may find that wearing these shoes and special insoles provide relief to your arthritis pain and also reduce load on your joints that could be beneficial to your arthritis. The information collected during this study may be of future benefit to others or yourself.

At the end of the study you will be asked to return the study insoles and insole accessories. You will be allowed to keep the study shoes and the standard insole.

What other options are there?

Instead of participating in this study, you may choose another form of treatment such as:

- Oral pain medications,
- Standard steroid injection,
- Physical therapy/activity modifications, or
- Surgery.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. The study doctor and study staff will have access to the confidential data identifying you by name. In all study records, you will be identified only by initials and/or a subject number. The sponsor of this study, The Arthritis Foundation, may request data pertaining to the study. Data provided to this organization will be identified by the subject number only.

If you withdraw from this study, the data already collected from you may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings. To conduct this study, we acquire photographs and videos of you standing and walking. In the event that a photograph or video is used for disseminating information to the scientific community, the individual's face and other distinguishing features such as birthmarks, scars, or tattoos will be obscured. In order to conduct the study, the study doctors will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctors will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

A description of this study will be available on http://www.CLINICALTRIALS.gov, as required by U.S. law. This Website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website anytime.

What are the costs of your participation in this study?

There will be no cost to you or your health insurance for any procedures performed for the purpose of this study alone. The study doctor, through a grant, will pay for the cost of study visits and all study-related procedures including the walking tests, x-rays, shoes, insoles, and insole accessories.

What financial disclosure(s) apply to this study?

Rush University Medical Center is being paid by Arthritis Foundation to conduct this research. A portion of this money may go to the study doctor to compensate for other institutional research related costs.

Research studies like this one are designed to determine whether the shoe and special insole affects the way you walk. Rush is the sole owner of some of the technology used in the shoe. Dr. Shakoor (a co-investigator in this study) is a co-inventor of the shoe. Rush University will receive a part of profits from any sales of this device (shoe) and a portion of Rush's revenue will be distributed to Dr. Shakoor, as required under Rush Intellectual Property Policy.

It was considered that the additional payments to Dr. Shakoor were unlikely to affect your safety and/or scientific quality of the study. This recommendation was given to the IRB for its review and approval of this study. If you would like more information, please ask Dr.Shakoor.

Will you be compensated or paid?

You will be compensated a total of $150.00 in gift cards, and will not exceed that amount, for your completion of all study visits. You will receive a $50 gift cards after the completion of each visit. Once you've completed your 3rd and final study visit and returned the special shoe insole and insole accessories, you will receive the final $50 gift card.

If you have any questions about your compensation, you should talk to the study doctor or a member of the study staff. You must return the shoe insole and the insole accessories. In the event you are unable to return the study insole and insole accessories, you will not be compensated for any future study visits.

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

The Arthritis Foundation has no program for financial compensation or other forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: Markus Wimmer, 312-942-2789. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT:

Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:
I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

Signature of Individual Obtaining Consent	Date of Signature

☐ *Check here if the Individual Obtaining Consent observed the signing of this consent document and can attest, to the best of their knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily. By checking this box, the Individual Obtaining Consent does not need to sign on the Witness signature line (below).*

SIGNATURE BY WITNESS/TRANSLATOR
(for use if this consent is being used as a written summary of the research along with a short form consent OR when the person obtaining consent is not the witness):

I observed the signing of this consent document and attest that, to the best of my knowledge, the person signing the consent form is the subject and the person signing the form has done so voluntarily.

Signature of Witness/Translator	Date of Signature

☐ Check here if a separate witness signature is not necessary.

SIGNATURE OF THE PRINCIPAL INVESTIGATOR

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

Signature of the Principal Investigator	Date of Signature

☐ Check here if Principal Investigator obtained consent and a separate signature is not required.